

Applicants: Taka Aki Sato and Junn Yanagisawa  
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REMARKS

Claims 121-141 are pending in the subject application. By this Preliminary Amendment, applicants have canceled claims 133-139, and have amended claim 121. Accordingly, claims 121-132, 140 and 141 will be pending in the subject application upon entry of this Preliminary Amendment.

Applicants hereby request that the Information Disclosure Statement filed August 15, 2002 in connection with the subject application be considered upon entry of this Preliminary Amendment.

In view of the arguments below, applicants maintain that the Examiner's rejections have been overcome, and respectfully request that they be withdrawn.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 121-141 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Examiner states that the specification fails to teach peptides that "consist essentially of" the sequences that are set forth in the claims. Specifically, the Examiner alleges that in the case of polypeptides, there is no difference between the scope of meaning of the phrase "consisting essentially of" and that of "comprising", unless the

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specification specifically defines the meaning of the phrase relative to a particular sequence.

In response, but without conceding the correctness of the Examiner's rejection, applicants note that amended claim 121 does not recite the language objected to, and claim 139 has been canceled, thereby obviating the rejection.

In view of these remarks, applicants maintain that claims 121-132, 140 and 141 satisfy the requirements of 35 U.S.C. §112, second paragraph.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 121-141 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response, applicants respectfully traverse the Examiner's rejection.

The test for enablement is whether one skilled in the art could, at the time of the invention, make and use the claimed invention based on the disclosure and the information known in the art without undue experimentation. Applicants maintain that the claimed invention satisfies the test for enablement, and that the Examiner has not set forth sufficient grounds for concluding otherwise.

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The subject invention comprises a method for identifying compounds that inhibit the binding of a signal transducing protein with a cytoplasmic protein. This invention is based, at least in part, on applicants' surprising discovery of the new consensus sequence (S/T)-X-(V/I/L) composed of only three amino acids found in the carboxyl-terminus of signal transducing proteins that bind to PDZ domains of cytoplasmic proteins. Accordingly, the invention may be practiced using a signal transducing protein that contains a sequence within the consensus sequence to find compounds that will alter the binding of the carboxyl terminus domain.

In support of the rejection, the Examiner alleges that the specification does not reasonably enable the claimed methods because it allegedly fails to teach the biological significance of any combination of signal transducing proteins and cytoplasmic proteins other than that of Fas and FAP1. Therefore, the Examiner concludes that given the breadth of the claims with respect to the scope of the disclosure of the specification and what is known in the prior art, one skilled in the art would be forced to engage in undue experimentation in order to make or use the subject invention.

Applicants strongly disagree with the Examiner's position.

Applicants maintain that the biological significance of combinations in addition to Fas/FAP1 need not be known in order for the enablement requirement to be satisfied. All that is required is that one skilled in the pertinent art would, at the time of filing, be able to measure under the specified circumstances the binding between two specific types

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of proteins as detailed in the specification. In view of the specification, the biological significance of the binding, or lack thereof, of any combinations of these proteins is irrelevant for purposes of enablement.

Nevertheless, applicants note that teachings other than that of the Fas/FAP1 combination can be found both in the specification and in the prior art at the time of filing. The subject specification discloses, *inter alia* on page 32, lines 3-30, page 9, lines 1-35 and Figures 8-12, the specific binding of the p75 receptor to FAP1 and its role in the apoptotic signal transduction in neuronal cells. Moreover, Table 1 on page 3 of the specification details protein interactions involving the PDZ domains of several signal transducing proteins such as the NMDA receptor and the K<sup>+</sup> channel. The specification also teaches additional signal transducing proteins that contain the necessary binding sequence. These include the CD4 receptor (Figure 7B), the serotonin 2A and 2B receptors (Figures 7F and 7G, respectively), the human colorectal mutant cancer protein (Figure 7D), protein kinase C (Figure 7E) and the adenomatosis polyposis coli tumor suppressor protein (Figure 7H). Furthermore, applicants note that the prior art, at the time of filing, disclosed NMDA receptors, K<sup>+</sup> Channels, CD4 receptors, serotonin receptors, and p75 receptors and the cytoplasmic proteins with which these receptors are associated, and the function of such association. According to M.P.E.P. § 2164.05(a), "[t]he state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling". *In re Gunn*, 537 F.2d 1123, 1128, 190 USPQ 402, 405 (CCPA 1976). However, the

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specification "need not disclose what is well-known to those skilled in the art". In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991).

Accordingly, applicants maintain that the direction and detailed working examples disclosed in the subject specification in combination with the state of the prior art and the level of one of ordinary skill at the time of filing satisfy the requirements for enablement of 35 U.S.C. §112, first paragraph.

The Examiner further rejected claims 121-132, and 139-141 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that applicants had possession of the invention.

Specifically, the Examiner alleges that claims 121 and 139 recite "consisting essentially of 3-13 amino acids having at its carboxyl terminus the amino acid sequence (S/T)-X-(V/I/L)" as a limitation of the structure of a signal transducing protein which was not in the specification as originally filed.

In response, but without conceding the correctness of the Examiner's rejection, applicants again note that amended claim 121 does not recite the language objected to, and claim 139 has been canceled, thereby obviating the rejection.

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In view of these remarks, applicants maintain that claims 121-132, 140 and 141 satisfy the requirements of 35 U.S.C. §112, first paragraph.

Rejection Under 35 U.S.C. §102(e)

The Examiner rejected claims 121-132 and 139-141 under 35 U.S.C. §102(e), as allegedly anticipated by Reed et al (U.S. Patent No. 5,876,939).

Specifically, the Examiner alleges that claims 121-132 and 139-141 are interpreted as methods encompassing the Fas receptor, because the claims are drawn to proteins consisting essentially of 3-13 amino acids having at its carboxyl terminus the amino acid sequence (S/T)-X-(V/I/L).

In response, but without conceding the correctness of the Examiner's rejection, applicants note that amended claim 121 does not provide for methods encompassing the Fas receptor, and claim 139 has been canceled, thereby obviating the rejection.

In view of these remarks, applicants maintain that claims 121-132, 140 and 141 satisfy the requirements of 35 U.S.C. §102(e).

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Conclusion

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the rejections, and earnestly solicit allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with this Preliminary Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being transmitted this date by facsimile to:

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